

## Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-05

/059 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

EUR/EX:JCLARK(INFO)

ARA/LA:KDACKERMAN(INFO)

AF/EX:GKRYZA(INFO)

EA/EX:RSCARRITT(INFO)

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FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES PRIORITY

AMEMBASSY TEL AVIV PRIORITY

AMEMBASSY CANBERRA

AMEMBASSY BRUSSELS

AMEMBASSY BOGOTA

AMEMBASSY SAN JOSE

AMEMBASSY BONN

AMEMBASSY BRASILIA

AMEMBASSY PRETORIA

AMEMBASSY TOKYO

AMEMBASSY AMMAN

AMEMBASSY MEXICO

AMEMBASSY LIMA

AMEMBASSY LONDON

AMEMBASSY CARACAS

USINT BAGHDAD

AMCONSUL RIO DE JANEIRO

AMCONSUL SAO PAULO

AMCONSUL JOHANNESBURG

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E.O. 11652: N/A

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TAGS: OGEN, ETRD, TBIO, AR, AS, BE, BR, CO, CS,

SUBJECT: FDA ADVISORY - BLOOD LEAKS IN DISPOSABLE HEAT EXCHANGERS (RECALL NO. T-052/053-6)

1. FDA ADVISES THAT:

PRODUCTS INVOLVED:

A. DISPOSABLE NORMOTHERMIC HEAT EXCHANGER, CATALOG NO. 5M0335 (RECALL NO. T-052-6)

B. DISPOSABLE HYPOTHERMIC HEAT EXCHANGER, CATALOG NO. 5M0338 (RECALL NO. T-053-6)

LOT: ALL LOTS

MANUFACTURER:

TRAVENOL LABORATORIES, INC.  
ARTIFICIAL ORGANS DIVISION  
WILSON ROAD AND RT. 120  
ROUND LAKE, ILLINOIS

RECALLING FIRM:

TRAVENOL LABORATORIES  
ONE BAXTER PARKWAY  
DEERFIELD, ILLINOIS 60015

REASON FOR ADVISORY (RECALL): THE FIRM RECEIVED SEVENTEEN COMPLAINTS. AMONG THESE WERE TWO MAJOR BLOOD LEAKS BETWEEN THE CORE AND BLOOD SIDE COVER DURING OPEN HEART SURGERY. NO PATIENT INJURIES OR DEATHS HAVE OCCURRED.

2. ON DECEMBER 15, 1975, THE FIRM ISSUED A MAILGRAM WHICH STATED THAT THERE WAS A NEED FOR A FIELD CORRECTION FOR TRAVENOL DISPOSABLE HEAT EXCHANGERS. THE FIRM STATES THAT A BLOOD SIDE REINFORCING CLAMP HAS BEEN DEVELOPED FOR USE WITH TRAVENOL DISPOSABLE NORMOTHERMIC UNCLASSIFIED

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AND HYPOTHERMIC HEAT EXCHANGERS FOR USE WITH THE TWO MEMBRANE OXYGENATOR SYSTEM. THESE HEAT EXCHANGERS SHOULD NOT, REPEAT SHOULD NOT, BE USED WITHOUT THIS CLAMP. THE MAILGRAM FURTHER STATES THAT UNTIL THESE CLAMPS ARE AVAILABLE, IT IS SUGGESTED THAT YOU USE A PERMANENT TYPE HEAT EXCHANGER, REMEMBERING THAT WITH THE TWO MEMBRANE OXYGENATOR SYSTEM, A PERMANENT HEAT EXCHANGER SHOULD BE POSITIONED BETWEEN THE VENOUS PUMP

AND THE OXYGENATOR.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY ARE FAMILIAR WITH THE DETAILS OF THE RECALL AND THE CONTENTS OF THE MAILGRAM ISSUED BY TRAVENOL. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY SHOULD BE DIRECTED TO THE FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

FARMACIA REX  
CORDOBA 2401  
BUENOS AIRES, ARGENTINA

TRAVENOL LABORATORIES PTY., LTD.  
P.O. BOX 88  
TOONGABBIE N.S.W., AUSTRALIA

S A TRAVENOL LABORATORIES N V  
BOULEVARD HOURAING  
7860 LESSINES, BELGIUM

AMBRIEX SOUTH AMERICA  
RUA CEARA 104  
RIO DE JANEIRO, BRAZIL

TRAVENOL PRODUTOS HOSPITALARES LTDA  
RUA INHAMBU 1091-MOEMA  
CEP 04520 SAO PAULO, BRAZIL

LABORATORIOS TRAVENOL SOUTH AMERICA  
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APARTADO AEREO 2446  
CALI, COLOMBIA

LABS TRAVENOL S A  
SAN JOSE, COSTA RICA

TRAVENOL INT'L GMBH  
POSTFACH 113  
D-8000 MUNICH 2  
GERMANY

MEDICAL CITY  
RENAL DIALYSIS UNIT  
BAGHDAD, IRAQ

TRAV TRADING CO. LTD.  
ASHDOD, ISRAEL

SUMITOMO CHEMICAL CO.  
15 5-CHOMO  
OSAKA, JAPAN

KING HUSSEIN MEDICAL CENTRE  
JORDAN ARMED FORCES  
AMMAN  
AMMAN, JORDAN

TRAVENOL S A AP POSTAL 13-279  
MEXICO 13 DF, MEXICO

LABORATORIOS UNIDOS SOUTH AMERICA  
AVDA BOLIVAR 561  
PUEBLO LIBRE  
LIMA, PERU

KEAGRAMS LIMITED  
P.O. BOX 256  
JOHANNESBURG, SOUTH AFRICA

TRAVENOL LABORATORIES, LTD.  
CAXTON WAY, THETFORD  
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NORFOLK, ENGLAND

LABORATORIOS BAXTER CA  
APDO 68739 ZENA 10  
CARACAS, VENEZUELA KISSINGER

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 25 FEB 1976  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1976STATE045263  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.: AMS  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D760071-0376  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1976/newtext/t19760213/aaaaalca.tel  
**Line Count:** 206  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
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**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
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**Review Authority:** castelsl  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 14 JUL 2004  
**Review Event:**  
**Review Exemptions:** n/a  
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04 MAY 2006

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - BLOOD LEAKS IN DISPOSABLE HEAT EXCHANGERS (RECALL NO. T-052/053-6)  
**TAGS:** OGEN, ETRD, TBIO, AR, AS, BE, BR, CO, CS, TRAVENOL LABORATORIES  
**To:** BUENOS AIRES MULTIPLE  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006